JAN 11 2001

K003513

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name:	ICU Medical
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Contact Name	Salvadore F. Palomares RAC
Date Prepared	January 4, 2001

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K003513

Trade Name:	Taxol Administration Set
Common Name:	Intravenous Administration Set
Classification Name:	Same

Equivalent Devices:
- Baxter Solution Administration Set (K981792)
- IMED Corp Vented/Nonvented Gemini Administration Set (K973167)
- IMED Corp Vented/Nonvented Gemini Administration Set (K944320)
- ICU Medical Primary IV Administration Set (K964435)

Device Description:
The Taxol Administration Set is an administration set designed for the infusion of antineoplastic agents such as Taxol® (Paclitaxel). The package insert for paclitaxel recommends that the drug be administered parenterally through a polyethylene lined set because of concern with diethyl-2-hexylphthalate (DEHP leaching from DEHP plasticized PVC. The set contains a bag spike/drip chamber; polyethylene lined tubing, inline 0.22 μm filter, clamp, injection site and a luer adapter. Most of these components are traditionally found in administration sets but the tubing and filter are components specifically identified in the drug package insert for paclitaxel.

Intended Use:
The Taxol Administration Set is intended to be used to administer solutions containing the chemotherapeutic drug paclitaxel, but may be used for general solution administration as well.

Biocompatibility:
The materials used to manufacture the Taxol Administration Set comply with ISO 10993 or will comply with the standard prior to the initial distribution of the device.

Summary of Technological Characteristics of the New Device to Predicate Device
The device is similar to the current manufactured Baxter Solution Administration Set (SE-K981792). They use similar components, but the Taxol Administration Set uses cyclohexanone as the bonding agent versus TEHTM used in the Baxter device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2001

Mr. Salvadore F. Palomares
Manager of Regulatory Affairs
ICU Medical, Incorporated
951 Calle Amanecer
San Clemente, California 92673

Re: K003513
Trade Name: Taxol Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 13, 2000
Received: November 14, 2000

Dear Mr. Palomares:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k): K003513

Device Name: **Taxol Administration Set**

Indications for Use: The Taxol Administration Set is intended to be used to administer solutions containing the chemotherapeutic drug paclitaxel, but may be used for general solution administration as well.

Concurrence of CDRN, Office of Device Evaluation (ODE)

Prescription Use ___X___ or _____Over the Counter Use
(Per 21 CNR 801.109)

Patricia Cucente

(Division Sign-Off)
Division of Dental, Infection Control, and
General Hospital Devices
510(k) Number K003513